

### **REMARKS**

Applicant has amended the specification to delete the hyperlink-portion of the reference at page 14, line 5, although the web-site referred to was governmental web site, not a commercial web site. This amendment is clerical in nature. Accordingly, no new matter has been added, and the entry of the amendment is respectfully requested.

Claim 1 has been amended to refer to “antibody that specifically binds human” Mi. Support for the amendment can be found throughout the specification, particularly at page 13, lines 25-26. Accordingly, no new matter has been added, and the entry of the amendment is respectfully requested.

New claims 18-23 have been added. These claims refer to “region of human microphthalmia (Mi) unique to human Mi that binds human Mi.” Support for this amendment can be found throughout the specification, particularly at page 13, lines 13-17 and the examples. Accordingly, no new matter has been added, and the entry of the amendment is respectfully requested.

The specification was objected to because page 14, line 5 contained an embedded hyperlink. Applicant has amended the specification to remove the hyperlink. In light of the amendment, Applicant submits that the objection has been overcome.

Claims 1, 4, 13, and 16-17 were newly rejected under 35 U.S.C. 112, first paragraph, as non-enabled. The Examiner interpreted the claim to encompass “any antibody that binds to microphthalmia and that cross reacts with any protein that comprises epitopes found in microphthalmia” (March 25, 2005 Office Action, page 2, last sentence of the first full par.).

Applicant respectfully disagrees and submit that the rejection be withdrawn for the following reasons.

Applicant submits that the skilled artisan reading the claim and seeing that it is directed to determining whether Mi is being expressed or not would know that the antibody is not a non-specific antibody that binds equally to a range of proteins but that selectively binds Mi.

To expedite prosecution, Applicant has amended claim 1 to make explicit that which was believed implicit. Namely, that the antibody selectively binds to Mi. This concept is discussed throughout the specification, particularly at pages 12-14 and the examples, where an example of such an antibody is shown. Applicant, as acknowledged by the Examiner, has established that

there is a high correlation between the expression of Mi in a malignant cell (p. 5. lines 19-21), and that cell being of melanoma origin. Moreover, the specification teaches that the antibody or antibody fragments should be **specific to Mi** (page 13, lines 24-27). In light of the claims and the specification, the skilled artisan understands that such antibodies do not substantially cross-react with other proteins, such as TFEB, TFEC, TFE3, and other bHLH-ZIP factors.

Determining antibody specificity to its intended target is an integral part of production of any antibody. In light of the discussion of Mi specific antibodies in the specification and the ordinary skill in the art of antibody production at the time of filing the application, the Examiner's extensive discussion regarding proteins that have some homology to Mi, such as TFEB, TFEC, TFE3, and other bHLH-ZIP factors, such as Myc would be something that the skilled artisan would avoid. Moreover, even if there is some cross-reactivity leading to some false positives, 100% accuracy is not what is required for patentability. The claim is directed to a **screening** method that tells you whether a malignant cell is **indicative** of cancer. A skilled artisan, having read the instant specification and thus knowing that Mi is a marker for melanoma, would know exactly how to do to produce a spectrum of Mi-specific antibodies and how to use such antibodies in screening for malignant cells for melanoma.

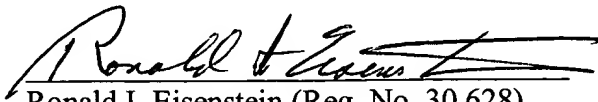
In light of the discussion above and the claim amendments, Applicant respectfully submits that the rejection should be withdrawn.

Applicant greatly appreciates the Examiner's statement regarding claim 14, although it was objected as being dependent of rejected claims. Applicant respectfully submits that the objection to claim 14 should thus be withdrawn because of the amendment to claim 1.

Applicants submit that all the claims comply with 35 U.S.C. §112.

Accordingly, Applicant respectfully submits that all claims are in condition for allowance. Early and favorable action is requested.

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